LU-9J

CERTIFIED MAIL:
RETURN RECEIPT REQUESTED

Ms. Lucy S. Wang
Associate Environmental Consultant
Eli Lilly and Company, Tippecanoe Laboratories
1650 Lilly Road
Lafayette, Indiana 47909-9201

RE: Determinations and Comments Regarding Proposed End Point Criteria
Eli Lilly and Company, Tippecanoe Laboratories
IND 006 050 967

Dear Ms. Wang:

We have reviewed the Site – Specific and Point of Compliance End Point Criteria which Lilly has presented in its October 2007 *Corrective Measures Study Report* and in Lilly's correspondence previous to the report. Our determinations and comments on the End Point Criteria are as follows:

SITE – SPECIFIC END POINT CRITERIA

In a number of letters to U.S. EPA and in subsequent discussions with EPA and IDEM, Lilly has proposed the use of a set of constituent-specific groundwater concentration limits for its site in Lafayette, Indiana (Jan. 26, 2006; June 27, 2006; Dec. 8, 2006). Lilly refers to these concentration limits as health risk-based "Site-Specific End Point Constituent Criteria." Lilly is proposing that these concentrations should be used as groundwater concentrations which would be acceptable upper end "no further action" limits at all site groundwater monitoring wells which are upgradient of those groundwater wells which will be used to evaluate the "Point-of-Compliance" groundwater concentrations.

In discussions with Lilly and in response letters (May 5, 2006; Sept. 13, 2006), the U.S. EPA has expressed concerns about the objective and utility for applying these "Site-Specific End Point Criteria" for the Lilly site. The major concerns are summarized below:

1) The calculated End Point Criteria are based on ingestion exposure to groundwater by workers. As described in the letter dated January 26, 2006, Lilly calculated the End Point Criteria on a risk-based scenario in which site workers would have very infrequent contact with groundwater and would be exposed by incidental ingestion. The use of this scenario resulted in the calculation of End Point Criteria values in the high mg/liter (ppm) range for most constituents. In discussions with Lilly, EPA expressed concern that the calculation of high allowable groundwater concentration limits at upgradient wells is not a suitable approach for ensuring that downgradient groundwater concentration limits at point-of-compliance wells would not become excessive at some future time point. Lilly has not submitted any groundwater modeling or other information which would alleviate EPA's concerns about unacceptable future point-of-compliance groundwater constituent concentrations.

2) The calculated End Point Criteria do not include the pathway for inhalation exposure to volatile groundwater contaminants by workers. In discussions with Lilly and a subsequent response letter (May 5, 2006), EPA expressed the concern that the calculation of End Point Criteria did not include the evaluation of inhalation exposure to Volatile Organic Carbon constituents in groundwater. EPA was concerned that End Point Criteria based on inhalation exposure to volatile chemicals could be more stringent (lower) than Concentrations based on incidental ingestion exposure. EPA requested Lilly to evaluate the need for including the inhalation exposure pathway based on the equivalent target risk levels used to calculate the original values (i.e., cancer of 1E-05 and Hazard Quotient of 1). Lilly submitted a response (June 27, 2006) which did not include the requested health risk evaluation for inhalation exposure. Instead, Lilly's response was to perform a vapor-constituent release model to ambient air using the original calculated End Point Criteria as the acceptable groundwater concentrations. The predicted constituent ambient air concentrations were compared to OSHA occupational limits (PELs or TWAs) and not to the requested risk-based target goals (i.e., cancer of 1E-05 and Hazard Quotient of 1). Consequently, Lilly has not actually evaluated the effect of the inhalation exposure pathway on the calculation of End Point Criteria.

3) For several constituents (8 out of 20), the calculated risk-based End Point Criteria were found to exceed the solubility limits of the constituents. Lilly proposed that the full solubility limit concentrations of those constituents should be adopted as the acceptable End Point Criteria. In subsequent discussions and correspondence with Lilly, EPA expressed the concern that solubility limits are not suitable criteria for End Point Criteria for the protection of groundwater resources and for providing assurance that downgradient groundwater concentrations at point-of-compliance wells would not become excessive at some future time point. The primary concern is the documented observation that as constituents approach their groundwater solubility limits, the constituents would be associated with the presence of free products (e.g., DNAPL or LNAPL). EPA presented Lilly with published evidence that site constituent concentrations as low as 1% of the solubility limits in groundwater at some sites have been shown to be associated with the occurrence of free product. As a compromise position, EPA proposed that a value of 10% of the solubility limit could be used as the starting point for proposing End Point Criteria (May 5, 2006). In subsequent correspondence (Dec. 8, 2006), Lilly rejected the EPA offer and proposed that the limit should only be reduced to 50% of the solubility limit as the acceptable End Point Criteria. In view of EPA's well stated concerns for any future free product releases at the Lilly site, Lilly's proposal is not acceptable.

4) The adoption of high End Point Criteria approaching the level at which free product might be encountered is questionable for other site-specific reasons. In a number of discussions and in written correspondence (e.g., Dec. 8, 2006), Lilly has stated that there is no evidence for concluding that free product releases are currently present beneath its plant site at any locations upgradient from the proposed groundwater Point-of-Compliance locations for the site. If the existing evidence supports Lilly's contention, then the adoption of End Point Criteria which exceed 10% of the solubility limit is not necessary.

Based on the above observations, EPA believes that further discussion of site-specific End Point Criteria, as presently proposed, is not warranted.

POINT OF COMPLIANCE END POINT CRITERIA

In the October 2007 *Corrective Measures Study Report* (CMS Report) ground water contaminants entering the open water column were adequately evaluated against water quality criteria. However, the CMS Report does not evaluate the impact of ground water contaminants (transported to sediment pore water) on benthic organisms.

The impact of ground water contaminants on benthic organisms dwelling in the river sediment (i.e., pore water) was identified (July 29, 2004, letter from EPA to Lilly, item #2 End point Criteria) as a concern and later at the April 27, 2006, meeting between Lilly, EPA and IDEM (also stated in the May 5, 2006, letter from EPA to Lilly).

Many of the Region 5 ESLs for sediment were developed using an equilibrium-partitioning (EqP) benchmark which is based on the chemical log octanol-water partition coefficient (log Kow) and water quality criterion that is intended to protect 95% of aquatic species. In this EqP approach, contaminants released from the sediment to the pore water use a water quality criterion as the protective benchmark for this pore water. This mechanism is described in U.S. EPA 2003b. Draft Technical Basis for the Derivation of Equilibrium Partitioning Sediment Benchmarks (ESBs) for the Protection of Benthic Organisms: Non-Ionic Organics. EPA-600-R-02-014. Office of Research and Development, Washington, DC. Examples are available in specific chemical ESB reports at:

http://www.epa.gov/nheerl/publications/

Since the ground water plume is the source of contaminants rather than the sediment, the contaminant concentration in the sediment pore water will be the same as the ground water plume concentration. No dilution is expected in the sediment pore water as transport from the ground water plume is assumed to be continuous.

Note that the purpose for sediment sampling under the April 30, 2003, work plan was to confirm that SVOCs have not accumulated in river sediment in the vicinity of past and present waste water outfalls. This effort did not collect sediment interstitial (i.e., pore) water and did not evaluate potential impacts from ground water plumes to sediment dwelling organisms.

The CMS Report needs to compare the contaminant concentrations in the ground water plume (representative sediment pore water) against the water quality criteria. This analysis will show if there is an impact from ground water contaminants on benthic organisms dwelling in the river sediment.

Section 2.3.2 (Region 5 ESLs) of the CMS Report needs revisions as described below.

1. The text and table on page 50 need the following revisions:

a. Revise the text as follows: In summary, the following table lists the EDLs and calculated *Great Lakes* Water Quality *Initiative Tier 2 (GLI-T2) values* for each target constituent.

b. Revise the table by replacing the right column heading with the following label: GLI-T2 Values (ug/L).

c. Replace the values in the right column with SCC values from the table on page 47. These values are:

Chemical	CAS#	GLI-T2 (SCC) Values (ug/L)
p-Chlorobenzotrifluoride (pCBT)	98-56-6	83
n,n-Diethylaniline (n,n-DEA)	91-56-6	5.6
Diethyl ether	60-29-7	1,100
Hexane	110-54-3	23
Tetrahydrofuran (THF)	109-99-9	8,400

d. Relocate the revised text and table to follow the table on page 47.

e. Following the relocated text and table (See comment 1d.), create two new subsections for the following topics:

Wabash River – Water
Wabash River – Sediment (This new section will follow the current text on page 49.)

2. New subsection on Wabash River – Sediment

Use the above information in paragraphs 2 through 6 to create this new subsection and use the values from the revised table (See comment 1c above.) as the benchmarks to protect benthic organisms in sediment for the Wabash River and Big Wea Creek.

3. Revise the table in Section 2.3.5 (Final POC EPC) on page 53

a. The column labeled “ESL / WQBS” will be changed to “ESL / GLI – T2” and the values identified in comment 1c (above) need to be used. A new column can be created to support the subsection on “Wabash River – Water” regarding the open water mixing zone in the Wabash River and Big Wea Creek.

b. The values under the column “POC Criteria” need to be revised for the following four constituents. Please note these four POC criteria were proposed in the December 8, 2006, letter (Refer to page 2.) from Lilly to EPA.

p-Chlorobenzotrifluoride (p-CBT)	83
n,n-Diethylaniline (n,n-DEA)	5.6
Diethyl ether (DE)	1,100
Hexane	23

Revisions to the CMS Report are to be submitted to this office and to the IDEM within ( ) days of receipt of this letter.

Please contact me at (312) 353-1248 or by e-mail at Heller.Donald@epa.gov if you have questions.

Sincerely,

Donald A. Heller, Corrective Action Project Manager
Corrective Action Section 1
Remediation and Reuse Branch

cc: Mario Mangino, RRB
Daniel Mazur, RRB
David Petrovski, RRB
Doug Griffin, IDEM
Paula Bansch, IDEM